## REMARKS

### Telephonic inquiry

Applicants called the Examiner's Office requesting a telephonic interview on May 18, 2011, to which the Examiner promptly responded on May 19, 2011. The Examiner requested that the telephonic interview be rescheduled to some other time in the future, when the Patent Office could make an initial assessment on the allowability of the claims in light of the substantive amendments presented herein. Applicants thank the Examiner for agreeing to reschedule the telephonic interview prior to the issuance of a second Office Action on the merits and thereby expedite the prosecution of the application.

### Claims

Claims 40–59 and 63–65 are pending. Claims 1–39 and 60–62 were previously cancelled without prejudice or disclaimer.

Claim 66 and 67 are added by this paper. It is submitted that insofar as the subject matter of the new claim involves method steps that are substantially similar to those recited in the elected claims, claim 66 should be rejoined with the elected claims.

### Claim amendments

The amendment of claims 50 and 58 is supported by the disclosure contained in, for example, original claim 50. The claims have been further amended to recite the art-accepted term for the biomolecules of the instant invention. Support for the amendment can be found in, for example, paragraph [0014] of the published US specification (US application pub. No. 20100162421).

Claims 63–65, which depend on claim 58, now read on the elected subject matter.

New claim 66 is supported by the disclosure contained in, for example, original claim 48. See also, for example, paragraphs [0080] and [0087] of the published US specification. New claim 67 is supported at least by the disclosure in the Examples.

It is respectfully submitted that the amendments do not recite new matter. Entry thereof is respectfully requested.

### Abstract

An abstract which is identical to the abstract that appears on the cover page of the

international application PCT/EP2004/007917 (of which the instant application is a US national stage entry under §371) is enclosed herewith.

It is submitted that no new matter is added in the enclosed abstract. Entry thereof is earnestly solicited.

**Rejection under 35 U.S.C. §112, ¶1 (Written description)**

At page 3 of the Office Action, it is alleged that "Claims 50 and 58 are not original claims and these claims have been substantively amended. No basis has been pointed to in support of these claims and none is apparent." This contention is respectfully traversed.

Claim 50 is directed to methods for the treatment of diabetes, obesity, metabolic syndrome or a method for the treatment of a metabolic disease or metabolic dysfunction, comprising administering to a subject in need thereof, a human pleiotrophin polypeptide or a functional fragment thereof. Claim 58 is directed to methods for (i) the treatment, alleviation and/or prevention of diabetes, obesity, and/or metabolic syndrome, (ii) the modulation of pancreatic development, and/or (iii) the regeneration of pancreatic cells or tissues in a subject in need thereof, comprising administering said subject with a medicament comprising an acceptable carrier and a human pleiotrophin polypeptide or a functional fragment thereof. Original claims 50 and 58, which recite these embodiments in Swiss-type (i.e., use) claim format, provide adequate basis for these claims. Nevertheless, the original specification also provides *explicit* disclosure for each and every embodiment of the claimed invention so as to enable a skilled worker to practice the claimed invention in its broadest possible scope.

To this end, paragraphs bridging [0013]-[0014] of the published specification (US pub. No. 20100162421) expressly teaches that the instant "invention describes secreted proteins that are specifically expressed in pancreatic tissues early in the development [and further] relates to the use of these genes and proteins in the diagnosis, prevention and/or treatment of pancreatic dysfunctions, such as diabetes, and other related diseases such as obesity and/or metabolic syndrome." The original specification further teaches that an example of such genes and proteins is "the secreted factor referred to as DG001 which is involved in pancreas development, regeneration, and in the regulation of energy homeostasis."

With respect to the structure and biological function of the protein, the specification teaches that DG001 corresponds to human pleiotrophin, a member of the cytokine/growth factor family of proteins, which is a secreted heparin-binding cytokine that signals diverse

functions involved with angiogenesis, neuorogenesis, cell migration, and mesoderm-epithelial interactions."

With respect to the use of DG001 polypeptides of the instant invention in prevention of diabetes, the Examiner is requested to review the disclosure in, for example, paragraph [0081] of the published specification. Therein, it is taught that "a DG001 product or the modulator/effector thereof may be administered preventively to patients at risk to develop beta-cell degeneration, like for example but not limited to patients suffering from diabetes type 2 or LADA in early stages." With respect to the treatment methods comprising administration of the DG001 polypeptide of the instant application, paragraph [0087] the specification teaches that "DG001 protein product and/or modulators/effectors thereof in a pharmaceutical composition to a subject in need thereof, particularly a human patient, leads to an at least partial regeneration of pancreatic cells."

Paragraph [0034] of the published specification provides a rationale to use the DG001 polypeptide of the instant application by teaching that "DG001 protein in preadipocytes has the potential to enhance adipose differentiation at a very early stage. Therefore, the DG001 protein might play an essential role in adipogenesis. The results are suggesting a role of DG001 in the regulation in human metabolism, for example, as effector/modulator (for example, enhancer) of adipogenesis. Thus, DG001 is a strong candidate for the manufacture of a pharmaceutical composition and a medicament for the treatment of conditions related to human metabolism, such as diabetes, obesity, and/or metabolic syndrome."

With respect to the activity of the DG001 polypeptide in the *in vitro* setting, the disclosure in Examples 6-8 and the results in Figure 3 collectively show that the addition of DG001 enriched supernatant of 293 cells onto embryonic stem (ES) cells induces the expression of insulin.

As such, contrary to the Examiner's contentions, the disclosure in the specification literally discloses the claimed use of the DG001 polypeptides of the instant application in the treatment, alleviation or prevention of diabetes and other metabolic disorders. Withdrawal of the rejection is respectfully requested.

**Rejection under 35 U.S.C. §112, ¶1 (enablement)**

The Examiner contends that the original specification fails to enable one skilled in the art to practice the claimed methods. Each of the Examiner's contentions are rebutted below.

Alleged lack of exemplification

The Examiner alleges that the specification does not disclose or exemplify administering DG001 polypeptide or a functional fragment thereof would treat any disease or condition embraced by the claims. This contention is incorrect. The disclosure in Examples 6–8 expressly teaches that contacting embryonic stem cells with the DG001 polypeptide of the instant invention leads to the differentiation thereof into insulin producing cells. To this end, paragraph [0179] of the published specification explicitly teaches that

> "the results shown in FIG. 3 clearly demonstrate a significant induction of the differentiation of insulin-producing cells, if DG001 is added on [sic at] later stages of differentiation. Thus, DG001 has a strong inductive effect on the differentiation of insulin-producing beta cells."

The specification provides further disclosure on correlation of *in vitro* studies and *in vivo* application of the DG001 polypeptides for the treatment of diabetes. To this end, paragraph [0053] of the specification teaches that

> "the diagnostic and therapeutic uses for the proteins of the invention nucleic acids and proteins of the invention are, for example but not limited to: (i) tissue regeneration *in vitro* and *in vivo* (regeneration for all these tissues and cell types composing these tissues and cell types derived from these tissues)."

Paragraph [0087] of the specification discloses that

> "beta cells or precursors thereof may be treated *in vitro* and implanted or re-implanted into a subject in need thereof. Further, other cells of the pancreas can be regenerated *in vivo* and/or *in vitro* to cure a certain condition. However, even moderate improvements in beta-cell mass can lead to a reduced requirement for exogenous insulin, improved glycemic control and a subsequent reduction in diabetic complications. In another example, the compositions of the present invention will also have efficacy for treatment of patients with other pancreatic diseases such as pancreatic cancer, dysplasia, or pancreatitis, if beta-cells are to be regenerated."

Therefore, contrary to the Examiner's contentions, the original specification provides explicit guidance and experimental evidence on the use of DG001 polypeptides of the instant application in the practice of the instantly claimed methods. In view of the detailed disclosure provided in Applicants' own specification and the replete information available in the art, the Office Action fails to demonstrate evidence to doubt the objective truth of statements contained in Applicants' specification regarding enablement. As clearly stated by *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971):

> As a matter of Patent Office practice, then a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented **must** be taken in compliance with the enabling requirement of the first paragraph of §112, **unless** there is reason to doubt the objective truth of statements contained therein relied on for enabling support. (Emphasis in original)

See also *In re Bundy*, 209 USPQ 48 (CCPA 1981). Thus, in the absence of sound scientific reasoning which adequately demonstrates a reason to doubt the veracity of statements in the specification, the requirements under 35 U.S.C. §112, ¶1 are presumed to be satisfied. In light of this disclosure, to assert a lack of enablement, the courts have placed the burden on the PTO to show otherwise. It is courteously submitted that the Patent Office has not presented any articulated scientific reasoning to refute the findings or the conclusions made in the specification or the supporting publications. In addition, no evidence has been presented to support the contention that the claimed molecules could not be used, in a manner that is commensurate with Applicants' claimed invention. Only unsupported allegations and conclusions regarding the "complexity" and "unpredictability" in the field of Applicants' endeavor are provided to support the contention.

*In vivo* evidence

The Office Action at page 6 alleges that "it would not be so predictable that the *in vitro* results of Example 8 could be extrapolated to enable the claimed methods." The contention that demonstration of the observed biological effects in an *in vivo* model is necessary for satisfying the enablement requirements under §112, ¶1 is without merit. Firstly, the Examiner has not provided any evidence to support its contention that the specification's demonstration of the biological effects of the pleiotrophin polypeptides in the *in vitro* setting does not correlate with the effects thereof *in vivo*. Absent such, the rejection is legally misplaced. See, Marzocchi discussed *supra*. Moreover, decades of scientific studies, both at the basic and clinical levels, have established that *in vitro* studies "reasonably correlate" with their *in vivo* counterparts. Furthermore, the patent law is in accord.

In *Cross v. Iizuka*, 224 USPQ 739 (Fed. Cir. 1985), discussed *supra* the court affirming the decision on reliance on *in vitro* data, and the decision stated that

> *in vitro* results with respect to the particular pharmacological activity are

> generally predictive of *in vivo* test results, i.e., there is a reasonable correlation therebetween. Were this not so, the testing procedures of the pharmaceutical industry would not be as they are (emphasis added).

The court in the *Cross* decision also noted the following

> Knowledge of the pharmacological activities of compounds is beneficial to the medical profession, and requiring Iizuka to have disclosed *in vivo* dosages in the Japanese priority application would delay and frustrate researchers by failing to provide an incentive for early public disclosure of such compounds, thereby failing to further the public interest.
> ...
> Successful *in vitro* testing will marshal resources and direct the expenditure of effort to further *in vivo* testing of the most potent compounds, thereby providing an immediate benefit to the public, analogous to the benefit provided by the showing of an *in vivo* utility (emphasis added).

The Federal Circuit in *Fujikawa v. Watanasin*, 39 USPQ.2d 1895 (1996), stated that

> all that is required is the test to be reasonably indicative of the desired pharmacological response. ... There must be a sufficient correlation between the tests and the asserted pharmacological activity so as to convince those skilled in the art, to a reasonable probability, that the novel compound will exhibit the asserted pharmacological behavior.

Also, the court in *Brana 51 F.3d 1560,* 34 USPQ2d 1436 (Fed. Cir. 1995) stated that

> it is our firm conviction that one who has taught the public that a compound exhibits some desirable pharmaceutical property in a standard experimental animal has made a significant and useful contribution to the art, even though it may eventually appear that the compound is without value in the treatment of humans.

Applicants also point to *In re Bundy*, 642 F.2d 430, 209 USPQ 48, (CCPA 1981), where the disclosure established the basic pharmacology for the compounds, but where no examples were provided. The *Bundy* specification stated that the compounds of the invention possessed activity similar to E-type prostaglandins. Nevertheless it was found that sufficient guidance as to use were given in the disclosure. The court held that "what is necessary to satisfy the how-to-use requirement of §112 is the disclosure of some activity coupled with knowledge as to the use of this activity." The same is respectfully requested.

Breadth of the genus of diseases

Without agreeing to any of the contentions set forth in the Office Action, the claims in their amended form recite treatment of diabetes (from the various types of pancreatic diseases

originally disclosed in the specification). See also claim 65. Applicant reserves the right to pursue cancelled subject matter in one or more continuation applications. Withdrawal of the contentions set forth in page 5 of the Office Action is respectfully requested.

Breadth of the genus of biomolecules

With respect to variant sequences, the Examiner alleges that the genus of DG001 polypeptides is large. Reconsideration of this rejection, in view of the foregoing amendments, further in view of the precedential opinion issued by the United States Board of Patent Appeals and Interferences (*Ex parte* Kubin, Appeal No. 2007-0819, B.A.P.I. 2007) is earnestly solicited. The facts in Kubin are applicable to the present case. In Kubin, the Examiner contended that "at least 80% identity language" in the absence of any working examples, other than a few representative species, fails to provide enablement of the claimed genus of molecules. See, page 10 of *Ex parte* Kubin. The Examiner alleged that specification did not teach "which 20% . . . of amino acid residues should be changed in order to maintain the biological functions." In response, Appellants argued that the specification disclosed "in detail how to: 1) make variants of SEQ ID NOs: 1 and 2; 2) calculate the percent identity between SEQ ID NOs: 1 and 2 and the variant sequence; and 3) test the variant sequence to determine [functional activity]." See, items 23 and 24 at page 13. Appellants further argued that in view of the high level of skill in molecular biology, methods of making the claimed nucleic acid sequences and screening for activity [were] known in the art and described in the specification and that the "experimentation involved to produce other sequences within the scope of the claims" and thus to practice the full scope of the claims would have been "well within the skill of those in the art." The amount of experimentation involved would have been routine and not undue. See, items 27–30 at page 14.

The Board of Patent Appeals and Interferences in reversing the enablement rejection concluded:

> "The amount of experimentation to practice the full scope of the claimed invention might have been extensive, but it would have been routine. The techniques necessary to do so were well known to those skilled in the art. *See, e.g., Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1360, 47 USPQ2d 1705, 1719 (Fed. Cir. 1998) ("test [for undue experimentation] is not merely quantitative . . . if it is merely routine"). A "patent need not teach, and preferably omits, what is well known in the art." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986). Thus, we conclude the Specification would have enabled the full scope of claim 73. (Emphasis added)

Likewise in the present application, Applicants disclose a genus of pleiotrophin polynucleotides having a disclosed sequence and polypeptides encoded thereby. Methods of obtaining other polypeptide sequences. Such techniques may involve the use of a computer or other biochemical means. For example, variant nucleic acid sequences could be generated via site-specific mutagenesis of SEQ ID NO: 1. Specific hybridization techniques may also be used to isolate these variant polynucleotide sequences. A skilled artisan could routinely utilize translation techniques for identifying polypeptides which are encoded by such variant polynucleotides (for example, using translation tools) and determining whether such polypeptides would meet the structural features of the genus of pleiotrophin proteins claimed herein. The genus of the molecules claimed herein is small enough that the skilled artisan can output each and every sequence using routine computational methods. Moreover, insofar as the structural determinants of the variant sequences are expressed in terms of sequence identity, the skilled worker can use routine techniques, such as homology mapping, to further identify candidate nucleotides which meet the structural aspects recited in the claims. Conserved amino acid substitutions, which were appreciated in the art, could be used as high-stringency filters. Additionally, as is routinely conducted in bioinformatics, variant sequences having an abrupt stop codon, no start codon, etc. can be removed from this pool. As for the functional aspects, the skilled worker could use high throughput screening of variant sequences, for example, using the biochemical assays described in Applicants' own specification. Other high-throughput techniques for studying exocytosis, for example, imaging techniques and the like, may also be utilized. A simple search on PUBMED can verify that reagents and methodologies used in such assays were known to the skilled worker before the earliest priority date. Therefore, the level of "experimentation involved to produce other sequences within the scope of the claims" and thus to practice the full scope of the claims would have been "well within the skill of those in the art."

In view of the aforementioned amendments and remarks, it is respectfully submitted that Applicants' disclosure provides more than sufficient guidance to objectively enable one of ordinary skill in the art to make and use the claimed invention with an effort that is routine with in the art.

Withdrawal of the rejection under 35 U.S.C. §112, ¶1, is respectfully requested.

**Rejection under 35 U.S.C. §112, ¶1 (written description)**

At page 5 of the Office Action, the Examiner (albeit improperly under the enablement rejection) alleges that:

> The specification discloses on page 5 that DG001 refers to human pleiotrophin. However, other portions of the specification refer to pleiotrophin from other species and sequence variants. The claims are not considered to be limited to the protein of SEQ ID NO: 2. In the absence of a clear and limiting definition of DG0001 polypeptide or a sequence identifier, the claims are interpreted as including all pleiotrophins and variants. The specification does not disclose the structure of all pleiotrophins that could be used in the claimed methods. It is not known what the structure of a functional fragment of a DG0001 polypeptide would be. It is noted that "DG001" is not an art understood term used in the prior art for this protein family.

This contention and the rejection based thereon are both respectfully traversed.

Biomolecules of the instant application

While applicants may not agree with the agency's interpretation of the elements necessary to meet the statutory requirements of 35 U.S.C. § 112, nonetheless, the pending claims have been amended to substantially conform to the exemplary claims that appear on PTO's new *Written Description Guidelines*. To this end, it is submitted that insofar as the specification provides a detailed written description of the term DG001 and the decision in Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 52 USPQ2d 1029 (Fed. Cir. 1999) expressly favors Applicants' use of such terms, the Examiner's contention that absent explicit recitation of SEQ ID NOs, the claims lack description of the claimed biomolecules is without merit. However, purely to expedite prosecution, Applicants have amended the claims to recite human pleiotrophin polypeptides. Applicants' amendment of the claims should not be construed as acquiescence to this or any other ground of rejection set forth in the present application.

It is submitted that present claim 1 conforms to exemplary claims 1 and 2 of Example 15 beginning on Page 51 of the *Training Materials* (Rev. 1, March 25, 2008) of the PTO's new *Written Description Guidelines*. The PTO's Example 15 provides a claim to a polynucleotide encoding a "Squeaker" protein. The exemplary specification discloses a working example in which a full-length cDNA was isolated from a mouse cDNA library. The complete cDNA

sequence (SEQ ID NO: 1) and predicted amino acid sequence (SEQ ID NO: 2) are disclosed. The specification states that the cDNA encodes a novel protein that the specification refers to as the murine "Squeaker" protein. The specification discloses a method for isolating human and other mammalian Squeaker cDNA sequences. However, the specification does not disclose any working examples showing isolation of other Squeaker cDNAs, and does not disclose any cDNA sequences other than the mouse sequence. Representative claims are as follows:

> Claim 1. An isolated nucleic acid comprising a nucleic acid sequence encoding a mammalian Squeaker protein.
> Claim 2. The isolated nucleic acid of claim 1 wherein said nucleic acid sequence encodes mouse Squeaker protein.
> Claim 3. The isolated nucleic acid of claim 1 wherein said nucleic acid sequence encodes the amino acid sequence of SEQ ID NO: 2.
> Claim 4. The isolated nucleic acid of claim 1 wherein said nucleic acid sequence comprises the sequence of SEQ ID NO: 1.
> Claim 5. The isolated nucleic acid of claim 1 wherein said nucleic acid sequence encodes human Squeaker protein.

The guidelines state that claims 2–5 satisfy the requirements set forth under §112, ¶1. With respect to claim 1, it is stated that disclosure of a single representative member (i.e., mouse Squeaker protein) is insufficient to provide written description for a genus (i.e., *mammalian* Squeaker protein), absent a detailed disclosure of the structural features shared by members of the genus. The guidelines further state that representative claim 5 does not comply with the statutory requirements allegedly because the exemplary specification only teaches one murine Squeaker protein and no human Squeaker proteins are disclosed. Contrary to the exemplary specification, the present specification's disclosure of human and mouse isoforms of pleiotrophin polypeptides and nucleic acids encoding such polypeptides, along with the disclosure of functional fragments thereof (e.g., at least 4, preferably at least 6 and up to 50 amino acids) provides adequate written description of the claimed genus. See, for example, paragraph [0042] of the published specification for a disclosure of the variant polypeptides recited in the claims. Thus, like the mouse Squeaker protein of representative claim 2, the pleiotrophin polypeptide of claims 50 and 58 are adequately described.

The PTO's contention that the disclosure of specific examples of human pleiotrophin polynucleotide sequences and polypeptides encoded thereby, i.e., SEQ ID NO: 1 which encodes SEQ ID NO: 2, fails to provide adequate written description for the genus of the claimed polypeptides is respectfully traversed. Firstly, this is different from *University of California v.*

*Lilly, 964 F.2d 1128* (Fed.Cir. 1997) or *University of Rochester v. Searle, 358 F.3d 1303* (Fed.Cir. 2004) where functional language was involved with insufficient structural details available for a chemical compound. These facts here are similar to those in *Capon v. Eshhar*, 76 USPQ2d 1078, 1082 (Fed. Cir. 2005) and *Falkner v. Inglis,* 448 F.3d 1357 (Fed.Cir. 2006). In these cases, the court held that even where there are no examples within the scope of a claimed genus, a written description exists where the elements of the members of the genus are known. Here, based on the complete disclosed human pleiotrophin polynucleotide sequence (i.e., SEQ ID NO: 1), variant sequences are *also* comprehensible without explicitly listing each and every sequence. The specification provides representative examples of polynucleotide sequences which fall within this genus of polynucleotides, for example, SEQ ID NO: 1 and degenerates thereof. Furthermore, in view of the detailed level of knowledge in molecular biology and the sophisticated tools available to the skilled worker, *any* variant sequence which meets the claimed structural (i.e., nucleotide sequence) can be can be generated. For example, the sequences can be generated using Lasergene Software available via DNAstar Inc. Additionally, functional features (e.g., ability to differentiate ES cells into insulin-producing cells, as taught by the present specification) of these variants can be routinely tested, for example, using assays that are described in the present specification. Explicit description is therefore not necessary.

It is therefore courteously submitted that Applicants' claims in the current form, fully comply with the statutory requirements of 35 U.S.C. §112, ¶1 with respect to written description. Withdrawal of the rejection is respectfully requested.

**Rejections under §102(e)**

Claims 50 and 58 are rejected under 35 USC §102(e) as allegedly anticipated by Colley et al. (US patent app. pub. No. 2003-0202960; hereinafter "the '960 publication"). This contention is respectfully traversed.

Colley's disclosure in the '960 publication is directed to the use of pleiotrophins for stimulating angiogenesis in a human or animal in need thereof. In the paragraphs spanning [0011], [0014] and [0015] of the '960 publication, Colley teaches using pleiotrophin for treating cardiovascular diseases, coronary artery diseases, ischemic heart diseases, vasculopathies, peripheral atherosclerotic diseases, osteoporosis or arthritis. Colley is silent on the use of pleiotrophin proteins in the treatment of diabetes or any other disease or condition recited in the claims. With respect to diabetes, it should be noted that the cited reference only teaches

treatment of wounds associated with diabetes. To this end, under [0037], Colley teaches that wounds associated with diabetes (such as diabetic ulcers) or those occurring in immunosuppressed or immunocompromised patients may be treated, for example, in patients undergoing cancer chemotherapy, patients with acquired immunodeficiency syndrome (AIDS), transplant patients, and any patients suffering from medication-induced impaired wound healing. Such a teaching, even at its broadest interpretation, is not equivalent to treatment of diabetes, as recited in the present claims. To this end, the Examiner is requested to review the administrative guidelines under MPEP §2131, which states that to support a rejection under §102, "the identical invention must be shown in as complete detail as is contained in the ... claim." See also *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989). Without such, the holding of anticipation cannot stand. Accordingly, Colley fails to anticipate the claimed invention. Withdrawal of the rejection is respectfully requested.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response to Deposit Account No. 13-3402.

Respectfully submitted,

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Attorney Docket No.: WEICKM-0053

Date: May 24, 2011